FEB 12 2004

K040066

510(K) SUMMARY FOR THE SIREMOBIL C 06

Submitted by:

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

January 13, 2004

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**
Ms. Nealie Hartman
51 Valley Stream Parkway
Malvern, PA 19355
Phone: (610) 448-1769
Fax: (610) 448-1787

2. **Device Name and Classification:**

Trade Name:	Siremobil C 06 (C06 is internal project name, final name assignment will be determined prior to FDA clearance)
Classification Name:	Mobile X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1720
Device Classification:	Class II
Product Code:	OXO & JAA

3. **Substantial Equivalence:**
The Siremobil C 06 is substantially equivalent to the following devices:

Predicate Device Name	*510(k) Number*	*Clearance Date*	*Comparable Properties*
Siemens Siremobil Compact	K963093	08/07/1996	• Hardware • Control Software • Intended use
Siemens Siremobil Iso-C	K973598	11/10/1997	• Hardware • Control Software • Intended use

4. Device Description:

The Siremobil C 06 is a mobile x-ray system which consists of a mobile C-arm configured with a high frequency generator, X-ray tube assembly, image intensifier, TV camera, film cassette attachment, laser target devices, electronics cabinet, a monitor trolley and digital image storage system which consists of the digital memory device, image monitor(s), and user interface. The system is equipped with a footswitch and a hand switch for radiation release in the five modes of operation: digital radiography, fluoroscopy, pulsed fluoroscopy, subtraction, and roadmapping.

5. Intended Use of the Device:

The Siremobil C06 is a mobile x-ray system intended for use in operating room, traumatology, endoscopy, intensive care station, pediatrics, ambulatory patient care and in veterinary medicine. The Siremobil 06 can operate in six different modes: Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy, Cassette Exposures, Digital Subtraction, and Roadmapping, which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of intra-medullary nail implant in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

6. Summary of Technological Characteristics of the Devices Compared to the Predicate:

The Siremobil C 06 is a modification to the Siremobil Compact. Mechanically the changes are minor in design and style. The X-ray generator, X-ray tube and Image Intensifier are identical with the currently cleared product.

The imaging chain reflects the current standard of 1024^2 image processing and display with flat screen monitors. It was originally cleared with a stationary X-ray system (Uroskop Access) and is in clinical operation since more than 2 years. An uninterruptable power supply provides additional safety to image and demographic data in the event of a power outage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ms. Nealie Hartman
Technical Specialist Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway J-15
MALVERN PA 19355

MAY 22 2012

Re: K040066
Trade/Device Name: Siremobil CO6
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO and JAA
Dated: January 13, 2004
Received: January 13, 2004

Dear Ms. Hartman:

This letter corrects our substantially equivalent letter of November 14, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

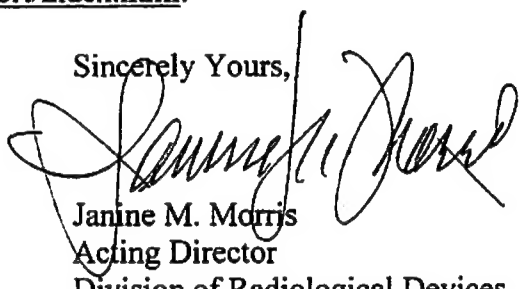
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K040066
Device Name: SIREMOBIL C06

Indications For Use:

The Siremobil C06 is a mobile x-ray system intended for use in operating room, traumatology, endoscopy, intensive care station, pediatrics, ambulatory patient care and in veterinary medicine. The Siremobil 06 can operate in six different modes: Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy, Cassette Exposures, Digital Subtraction, and Roadmapping, which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of intra-medullary nail implant in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040066